

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)
FENFLURAMINE/DEXFENFLURAMINE)) MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)

THIS DOCUMENT RELATES TO:)
)
SHEILA BROWN, et al.) CIVIL ACTION NO. 99-20593
)
v.)
)
AMERICAN HOME PRODUCTS) 2:16 MD 1203
CORPORATION)

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8379

Bartle, C.J.

January 7, 2010

James Donohue ("Mr. Donohue" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support his claim for Matrix Compensation Benefits ("Matrix Benefits").³

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Carol Donohue, Mr. Donohue's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or
(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is to be completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In July 2003, claimant submitted a completed Green Form to the Trust signed by his attesting physician, Ted M. Parris, M.D., F.A.C.C. Based on an echocardiogram dated July 30, 2002, Dr. Parris attested in Part II of Mr. Donohue's Green Form that claimant suffered from moderate mitral regurgitation, mitral annular calcification, and a reduced ejection fraction in the range of 50% to 60%.⁴ Based on such findings, claimant would be

3. (...continued)
contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

4. Dr. Parris also attested that claimant suffered from New York Heart Association Functional Class I symptoms. This condition,
(continued...)

entitled to Matrix B-1,⁵ Level II benefits in the amount of \$41,589.⁶

In the report of claimant's July 30, 2002 echocardiogram, the reviewing cardiologist, Richard J. Corbelli, M.D., F.A.C.C., observed that "[m]ild-moderate mitral regurgitation is noted on color flow imaging." Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22. Dr. Corbelli also found that "[t]he mitral valve demonstrates annular calcification"

In September 2005, the Trust forwarded the claim for review by Jeffrey S. Soble, M.D., one of its auditing cardiologists. In audit, Dr. Soble determined that claimant's level of mitral regurgitation was mild and that there was no

4. (...continued)
however, is not at issue in this claim.

5. A finding of mitral annular calcification requires the payment of benefits for a mitral valve claim to be reduced to Matrix B. See Settlement Agreement § IV.B.2.d.(2)(c)ii)d).

6. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust did not contest the attesting physician's finding of a reduced ejection fraction, which is among the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

reasonable medical basis for the finding of Dr. Parris of moderate mitral regurgitation. In support of this conclusion, Dr. Soble explained that "[t]here is only a single frame from a cineloop showing somewhat more MR than any of the real-time images. The loop is not present on any of the real-time video." Dr. Soble also concluded that claimant did not suffer from mitral annular calcification.

Based on the auditing cardiologist's diagnosis of mild mitral regurgitation, the Trust issued a post-audit determination denying Mr. Donohue's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), Mr. Donohue contested this adverse determination.⁷ In contest, claimant submitted a letter from Dr. Parris, who confirmed his original findings. Specifically, Dr. Parris wrote:

On the apical 4-chamber view, especially, there is an eccentric, posteriorly directed jet of mitral regurgitation that appears to occupy at least 25% or more of the left atrial area. In freezing the frame and doing simple outline, this is a true mitral regurgitation jet, and by my estimate occupies approximately 1/3 of the left atrium.

Claimant also argued that Dr. Soble inappropriately applied the reasonable medical basis standard by inserting his own subjective

7. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Mr. Donohue's claim.

opinion. Finally, Mr. Donohue asserted that the Settlement Agreement permits him to rely upon a single frame that demonstrates a moderate mitral regurgitant jet. In support of this argument, claimant cited PTO No. 2640 for the proposition that freeze-frame evaluation is commonly used and recognized by echocardiographers to evaluate the regurgitation of a valve.

The Trust then issued a final post-audit determination, again denying Mr. Donohue's claim. In its letter, the Trust asserted that the letter of Dr. Parris does not establish a reasonable medical basis for a finding of moderate mitral regurgitation because the attesting physician "does not address Dr. Soble's specific findings at audit, including his observation that no significant jet of mitral regurgitation was visible in real time - only in a single frame." Moreover, the Trust contested claimant's interpretation of PTO No. 2640, arguing that there, the court required a cardiologist to review multiple loops and still frames to reach a medically reasonable assessment of a claimant's level of mitral regurgitation. According to the Trust, a jet that lasts a single frame is representative of backflow, not true mitral regurgitation, because mitral regurgitation lasts throughout systole and can be seen in real time. Finally, the Trust argued that the court has held that claimants may not rely on echocardiogram reports that note "mild-moderate mitral regurgitation" to meet their burden of proving that there is a reasonable medical basis for the attesting

physician's determination of moderate mitral regurgitation. See PTO No. 5229.

Claimant disputed this final determination and requested that his claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Mr. Donohue's claim should be paid. On April 28, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6223 (Apr. 28, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on August 31, 2006. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor⁸ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Sandra V. Abramson, M.D., F.A.C.C., to review

8. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor's Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether Mr. Donohue has met his burden in proving that there is a reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of his claim, Mr. Donohue reasserts the arguments he made in contest, and argues further that the Trust disregarded the letter of Dr. Parris, in which the attesting physician noted that the apical four chamber view demonstrated moderate mitral regurgitation with an RJA/LAA ratio of at least 25%. Claimant argues that Dr. Soble improperly dismissed this jet because he did not see it in real time, even though, according to claimant, the Settlement Agreement permits a claimant to base his claim on any single apical view. Moreover, claimant suggests that the letter of Dr. Parris is evidence that he evaluated the level of mitral regurgitation as required by the

court. Claimant asserts that PTO No. 2640 does not require more than one true jet of moderate mitral regurgitation on which to base a claim, but only that a cardiologist review multiple loops and frames in order to ensure that the measured frame demonstrates "a true regurgitant jet rather than backflow or a phantom jet." Claimant notes that neither the Trust nor Dr. Soble has alleged that the jet seen by the attesting physician and auditing cardiologist was actually backflow or a phantom jet. Finally, claimant argues that a true regurgitant jet need not last throughout systole, as alleged by the Trust, but rather, it only must last through a portion of systole.

In response, the Trust reasserts the arguments addressed in the final post-audit determination. The Trust also asserts, without pointing to any medical findings, that claimant's study demonstrates marked persistence and decreased Nyquist settings. Finally, the Trust contends that Dr. Soble's findings were proper because the regurgitant jet demonstrated by the freeze frame of Dr. Parris was not visualized in real time.

The Technical Advisor, Dr. Abramson, reviewed claimant's echocardiogram and concluded that there was a reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. Specifically, Dr. Abramson stated in her Report:

In his Certification dated May 25, 2006, [Dr. Soble] opined that there is only a single frame from the cineloop showing more MR than any of the real-time images and that

this loop is not present on any of the real-time video..

In reviewing the transthoracic echocardiogram from 7/30/02, my visual estimate is that this is an eccentric jet of mitral regurgitation. Eccentric jets are more difficult to assess than central jets because they may not be present in every view. In the parasternal, apical-2-chamber and apical-long-axis views, there is only minimal mitral regurgitation. On the apical-4-chamber view, there are two cardiac cycles in the same cineloop, which demonstrate the eccentricity of this jet. I measured the mitral regurgitant jet and the left atrial area (in the same frame) in these two cardiac cycles. My measurements for mitral regurgitant jet area/left atrial area are $7.6 \text{ cm}^2/25.3\text{cm}^2$, and $9.3\text{cm}^2/30.7\text{cm}^2$. Both of these ratios are 30%, which is consistent with moderate mitral regurgitation. I believe that this moderate, eccentric jet represents the "true" mitral regurgitation even though it is not present in every view. I also agree with Dr. Parris and Dr. Corbelli that the echocardiogram demonstrates mitral annular calcification.

After reviewing the entire show cause record before us, we find that claimant has demonstrated a reasonable medical basis for his claim. The attesting physician reviewed Mr. Donohue's echocardiogram and found that claimant had moderate mitral regurgitation. Although the Trust challenged the attesting physician's conclusion, Dr. Abramson confirmed the attesting physician's finding of moderate mitral regurgitation.⁹ Specifically, Dr. Abramson concluded that "[t]here is a reasonable medical basis for the Attesting Physician's claim that James Donohue has moderate mitral regurgitation."

9. Despite an opportunity to do so, the Trust did not submit a response to the Technical Advisor Report. See Audit Rule 34.

As stated above, moderate or greater mitral regurgitation is present where the RJA in any apical view is equal to or greater than 20% of the LAA. See Settlement Agreement § I.22. Here, Dr. Abramson found that claimant's RJA/LAA ratio was 30% in two cardiac cycles in the apical four chamber view. Under these circumstances, claimant has met his burden in establishing a reasonable medical basis for his claim. Accordingly, we need not address claimant's remaining arguments.

Although the auditing cardiologist determined that there was no reasonable basis for the attesting physician's representation that claimant suffered from mitral annular calcification, claimant's attesting physician conceded, and the reviewing cardiologist found, the presence of mitral annular calcification. In addition, the Technical Advisor, Dr. Abramson, confirmed the presence of mitral annular calcification.¹⁰ As previously stated, the presence of mitral annular calcification requires the payment of a mitral valve claim on Matrix B.

For the foregoing reasons, we conclude that claimant has met his burden in proving that there is a reasonable medical basis for his claim and is consequently entitled to Matrix B-1, Level II benefits. Therefore, we will reverse the Trust's denial of the claims submitted by Mr. Donohue and his spouse for Matrix Benefits.

10. Despite an opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34.